# Exhibit H

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| MAINE AUTOMOBILE DEALERS ASSOCIATION, INC. INSURANCE TRUST, On Behalf of Itself and All Others Similarly Situated,<br><br>Plaintiff,<br><br>v.<br><br>A-S MEDICATION SOLUTIONS LLC; ACTAVIS PHARMA, INC.; AUROBINDO PHARMA USA, INC.; AVKARE, INC.; BRYANT RANCH PREPACK, INC.; CAMBER PHARMACEUTICALS, INC.; H. J. HARKINS COMPANY, INC.; HETERO LABS LTD.; HUAHAI U.S. INC.;MYLAN PHARMACEUTICALS INC.; NORTHWIND PHARMACEUTICALS, LLC; NUCARE PHARMACEUTICALS, INC.; PREFERRED PHARMACEUTICALS, INC.; PRINSTON PHARMACEUTICALS INC.; REMEDYREPACK INC.; SANDOZ, INC.; SCIEGEN PHARMACEUTICALS; SOLCO HEALTHCARE US, LLC; TEVA PHARMACEUTICALS USA, INC.; THE HARVARD DRUG GROUP, LLC; TORRENT PHARMACEUTICALS LTD.; and ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.,<br><br>Defendants. | CIVIL ACTION NO. _____ |

**CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

COMES NOW the Maine Automobile Dealers Association, Inc. Insurance Trust, on behalf of itself and a class of all other third-party payers similarly situated, complains against A-S Medication Solutions LLC; Actavis Pharma, Inc.; Aurobindo Pharma USA, Inc.; AvKare, Inc.;

Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; H. J. Harkins Company, Inc.; Hetero Labs Ltd.; Huahai U.S. Inc.; Mylan Pharmaceuticals Inc.; Northwind Pharmaceuticals, LLC; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Prinston Pharmaceuticals Inc.; RemedyRepack Inc.; Solco Healthcare US, LLC; Teva Pharmaceuticals USA, Inc.; The Harvard Drug Group, LLC; Torrent Pharmaceuticals Ltd.; Zhejiang Huahai Pharmaceutical Co., Ltd. as follows:

## SUMMARY OF THE ACTION

1. This is a proposed class action of Plaintiff and other third-party payers of health benefits who paid a substantial portion of the purchase price for health plan members to purchase angiotensin receptor blocker ("ARB") prescription drugs improperly contaminated with a carcinogen and ultimately recalled.

2. In July of 2018, the Defendant generic drug manufacturers and repackagers began a recall of millions of dollars of the widely-prescribed generic high blood pressure drug Valsartan — and Valsartan-containing products, including but not limited to Valsartan-Hydrochlorothiazide and Amlodipine-Valsartan (hereinafter referred to only as "Valsartan") — because it is tainted with a potent carcinogen, N-nitrodimethylamine ("NDMA"). Then, in October 2018, Defendants began a recall of the generic high blood pressure drug Irbesartan— and Irbesartan-containing products—because it was tainted with a potent carcinogen, N-Nitrosodiethylamine ("NDEA"). Additional recalls of Irbesartan were subsequently issued. In November 2018, Defendants began a recall of the generic high blood pressure drug Losartan— and Losartan-containing products— because it too was adulterated with NDEA. Additional recalls of Losartan were subsequently issued.

3. NDMA is a volatile, combustible, yellow, oily liquid, and has no therapeutic benefit. It should not have been present in Valsartan. NDMA-contaminated Valsartan does not meet U.S. Food and Drug Administration ("FDA") safety or drug manufacturing standards and cannot lawfully be sold in the United States. NDMA was introduced into Valsartan because it was contained in an active pharmaceutical ingredient ("API") manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. ("Zhejiang Huahai") and imported in bulk from China by Defendant generic drug manufacturers for use in manufacturing Valsartan sold in the United States.

4. NDEA is a carcinogenic and mutagenic organic compound found in tobacco smoke. NDEA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan do not meet FDA safety or drug manufacturing standards and cannot lawfully be sold in the United States. NDEA was introduced into Valsartan, Irbesartan, and Losartan because it was contained in API manufactured by Zhejiang Huahai and Hetero Labs Ltd. ("Hetero Labs") and imported from China and India by Defendant generic drug manufacturers for use in manufacturing Valsartan, Irbesartan, and Losartan in the United Sates.

5. Upon notice of the recall, insureds in the United States who had been prescribed contaminated Valsartan, Irbesartan, and Losartan sought and received replacement prescriptions for safe substitutes for the recalled Valsartan, Irbesartan, and Losartan, and discarded the remaining unused contaminated drug product that had been prescribed for them. The FDA estimates that more than one million patients in the United States were exposed to the contaminated drugs.

6. Plaintiff provides health benefit coverage, including a prescription drug benefit, to its members. The recall caused Plaintiff and similarly situated third-party payers ("TPPs") to

suffer economic loss in two ways. First, they incurred costs associated with the recall, including to replace the contaminated drugs with safe alternatives for their members, patient/physician office visits related to switching patients to substitute drugs, and any other unreimbursed costs for medical care associated with the recall. Among other things, Plaintiff and similarly situated TPPs paid twice for drugs to treat their members' medical conditions over the same time period when they should have paid only once. Second, NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan are worthless, unsafe, and not fit for sale or use in the United States. Yet, Defendants placed these drugs in the market and sold them to an unsuspecting public for four years. Plaintiff and similarly situated TPPs paid for these contaminated pharmaceuticals during the entire period. Plaintiff and similarly situated TPPs seek recovery of the amount paid by Plaintiff and TPP class members for NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan over the entire period of time it was sold by Defendants.

7. In this class action, Plaintiff, on behalf of itself and a class of similarly situated TPPs, requests an award of compensatory damages, punitive damages, interest, attorneys' fees, court costs, and such other relief as may be just and proper, arising from the presence of unsafe and illegal levels of NDMA and NDEA in certain lots of Valsartan, Irbesartan, and Losartan sold in the United States and paid for in whole or part by Plaintiff and a class of similarly situated TPPs.

## JURISDICTION AND VENUE

8. This court has jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d) because this is a class action, the aggregate amount-



 

in-controversy exceeds $5 million, the class comprises more than 100 plaintiffs, and at least one plaintiff class member is diverse from at least one defendant.

9. This Court has personal jurisdiction over Defendant Zhejiang Huahai. On information and belief, at all relevant times Zhejiang Huahai exercised a high degree of control over its subsidiaries including Prinston Pharmaceuticals Inc. ("Prinston"), Solco Healthcare US LLC ("Solco"), and Huahai U.S. Inc. ("Huahai U.S."). Huahai U.S.'s website touts that it "is engaged in . . . support to our Parent Company for manufacturing, R&D and marketing."[1]

10. On information and belief, at all relevant, times, Zhejiang Huahai, Huahai U.S., Prinston, and Solco were agents of each other and worked in concert with each other on the development, marketing, manufacturing, and distribution of valsartan through the United States. It appears that all four corporate entities shared corporate officers. For example, Hai Wang is listed on Solco's website as Solco's President. Hai Wang's personal LinkedIn page lists Hai Wang as the Vice President of Huahai U.S. Hai Wang is also listed on Prinston's website as its Senior Vice President of Business Development and Marketing.

11. Similarly, Bloomberg lists Du Jun, sometimes referred to as Jun Du, as the Vice Chairman of Zhejiang Huahai and the CEO of Huahai U.S. Jun Du is listed on Prinston's website as its CEO.

12. Prinston's website also lists Dr. Xiaodi Guo as its Chief Science Officer and Executive Vice President of Research and Development. But Xiaodi Guo's personal LinkedIn page lists him as the Chief Science Officer and Executive Vice President at Zhejiang Huahai.

[1] *About Us*, HUAHAI US INC., http://huahaius.com/about%20us.html (last visited Oct. 24, 2018).

Further, letters from the FDA to Huahai U.S. regarding one of Huahai U.S.'s ANDA submissions is addressed to Huahai U.S. Inc., Attention: Xiaodi Guo, Executive Vice President.

13. Chris Keith is Solco's Senior Vice President of Marketing and Business Development. He was previously Prinston's Vice President of Marketing and Business Development.

14. Huahai U.S., Prinston, and Solco all share the same corporate address in Cranbury, New Jersey.

15. This Court has personal jurisdiction over Defendants because Defendants are present in the United States, do business in the United States, have registered agents in the United States, and may be found in the United States. Defendants have sufficient minimum contacts in New Jersey, and otherwise avail themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is necessary and proper. Class members have paid for NDMA and/or NDEA contaminated Valsartan, Irbesartan, and Losartan manufactured or repackaged by Defendants in this District.

16. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b). A substantial part of the conduct, events, transactions, and claims occurred in this District. Defendants transact substantial business in this District and earned substantial compensation and profits from sales of the NDMA-contaminated Valsartan at issue in this Complaint within this District. In addition, the United States affiliates and subsidiaries of Zhejiang Huahai, which manufactured the NDMA-contaminated active ingredient used in Valsartan, are based in the District.

## PARTIES

17. Plaintiff, Maine Automobile Dealers Association, Inc. Insurance Trust, is a duly organized and existing 501(c)(9) tax-exempt trust that qualifies as a multiple employer welfare benefit plan or arrangement established or maintained for the purpose of offering or providing health benefits, including prescription drug coverage, to the employees of multiple employers and to their beneficiaries under the authority of the Maine Multiple-Employer Welfare Arrangements law, Title 24-A, Chapter 81, §§ 6601-6616 of the Maine Revised Statutes Annotated and the Employee Retirement Income Security Act of 1974. The Trust was organized in Maine and has its principal place of business in Maine.

18. The Trust is adopted to establish, implement and administer a multiple-employer welfare arrangement for the sole purpose of funding a plan of benefits, both on a self-funded basis and through the purchase of policies of insurance.

19. Defendant A-S Medication Solutions LLC ("A-S Medications") is a limited liability company organized under the laws of the State of Nebraska with a principal place of business at 224 North Park Avenue, Fremont, Nebraska.

20. Defendant Actavis Pharma, Inc. ("Actavis"), a subsidiary of Teva Pharmaceutical Industries Ltd., is a corporation organized under the laws of the State of Delaware with a principal place of business at 400 Interspace Parkway, Parsippany, New Jersey.

21. Defendant Aurobindo Pharma USA, Inc. ("Aurobindo"), a subsidiary of Aurobindo Pharma Ltd., is a corporation organized under the laws of the State of Delaware with a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey. Defendant Aurobindo manufactures API for Defendant ScieGen's Irbesartan.

22. Defendant AvKare, Inc. ("AvKare") is a corporation organized under the laws of the State of Tennessee with a principal place of business at 615 North 1st Street, Pulaski, Tennessee.

23. Defendant Bryant Ranch Prepack, Inc. ("Bryant Ranch") is a corporation organized under the laws of the State of California with a principal place of business at 1919 North Victory Place, Burbank, California.

24. Defendant Camber Pharmaceuticals, Inc. ("Camber") is a corporation organized under the laws of the State of Delaware with a principal place of business at 1031 Centennial Avenue, Piscataway, New Jersey.

25. Defendant H. J. Harkins Company, Inc. ("H. J. Harkins") is a corporation organized under the laws of the State of California with a principal place of business at 1400 West Grand Avenue, Suite F, Grover Beach, California.

26. Defendant Hetero Labs Ltd. is an Indian corporation with a principal place of business in Sanathnagar, Hyderabad, India. Hetero Labs manufactured NDMA-contaminated Valsartan API, and NDEA-contaminated Losartan API, which Defendant generic manufacturers sold to Plaintiff's insureds.

27. Defendant Huahai U.S. Inc. ("Huahai") is a New Jersey corporation, with its principle place of business located at 2001-2002 Eastpark Blvd, Cranbury, New Jersey 08512. Defendant Huahai is a wholly-owned subsidiary of Zhejiang Huahai Pharmaceuticals. At all relevant times, Huahai has been engaged in the manufacture, sale, and distribution of non-cGMP compliant generic valsartan in the United States.



 

28. Defendant Mylan Pharmaceuticals Inc. ("Mylan"), a subsidiary of Mylan N.V., is a corporation organized under the laws of the State of West Virginia with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia.

29. Defendant Northwind Pharmaceuticals, LLC ("Northwind") is a limited liability company organized under the laws of the State of Indiana with a principal place of business at 4838 Fletcher Avenue, Indianapolis, Indiana.

30. Defendant NuCare Pharmaceuticals, Inc. ("NuCare") is a corporation organized under the laws of the State of California with a principal place of business at 622 West Katella Avenue, Orange, California.

31. Defendant Preferred Pharmaceuticals, Inc. ("Preferred Pharmaceuticals") is a corporation organized under the laws of the State of California with a principal place of business at 1250 North Lakeview Avenue, Unit O, Anaheim, California.

32. Defendant Prinston Pharmaceuticals Inc. ("Prinston"), a subsidiary of Zhejiang Huahai Pharmaceuticals, is a corporation organized under the laws of the State of Delaware with a principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey. It is engaged in the development, sale, and marketing of generic pharmaceutical products in North America. Prinston was "spun off from Zhejiang Huahai Pharmaceutical Co., Ltd. in 2009."[2] At all relevant times, Prinston has been engaged in the manufacture, sale, and distribution of non-cGMP compliant generic valsartan in the United States.

[2] *History*, HUAHAI US INC., http://huahaius.com/history.html (last visited Oct. 24, 2018).



 

33. Defendant RemedyRepack Inc. ("RemedyRepack") is a corporation organized under the laws of the Commonwealth of Pennsylvania with a principal place of business at 655 Kolter Avenue, Indiana, Pennsylvania.

34. Defendant Sandoz, Inc. ("Sandoz") is a Colorado corporation with its principal place of business in Princeton, New Jersey.

35. Defendant ScieGen Pharmaceuticals, Inc. ("ScieGen") is a corporation organized under the laws of the State of New York with a principal place of business at 89 Arkay Drive, Hauppauge, New York, 11788.

36. Defendant Solco Healthcare US, LLC ("Solco"), a subsidiary of Prinston Pharmaceuticals Inc. and Zhejiang Huahai Pharmaceuticals, is a limited liability company organized under the laws of the State of Delaware with a principal place of business at 2002 Eastpark Boulevard, Suite A, Cranbury, New Jersey. Defendant Solco claims that its "products are manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements."[3] It is the "U.S. sales and marketing division of Prinston Pharmaceutical Inc."[4]

37. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), a subsidiary of Teva Pharmaceutical Industries Ltd., is a corporation organized under the laws of the State of Delaware with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Teva USA has reported the cost of the recall of NDMA-contaminated Valsartan at $46 million through the first nine months of 2018.

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[3] *Overview*, SOLCO HEALTHCARE U.S., http://www.solcohealthcare.com/about-solco.html#LeadershipTeam (last visited Oct. 24, 2018).

[4] *Subsidiary*, PRINSTON PHARMACEUTICAL, http://www.prinstonpharm.com/Subsidiary.html (last visited Oct. 24, 2018).

38. Defendant The Harvard Drug Group, LLC (d/b/a Major Pharmaceuticals) ("HDG") is a limited liability company organized under the laws of the State of Delaware with a principal place of business at 40600 Ann Arbor Road East, Suite 201, Plymouth, Michigan.

39. Defendant Torrent Pharmaceuticals Ltd. ("Torrent") is an Indian corporation with a principal place of business in Ahmedabad, Gujarat, India.

40. All of the generic drug manufacturer defendants identified in Paragraphs 19-39 of the Complaint have been identified by the FDA as responsible for Valsartan, Irbesartan, and Losartan products under recall as of December 31, 2018.[5] A spreadsheet made available by the FDA and attached as **Exhibit A** lists each of the responsible companies by name, identifies each Valsartan-containing product, the relevant National Drug Code ("NDC") for each product, lot numbers, and expiration date.

41. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai") is a Chinese corporation with a principal place of business in Linhai, Taizhou Zhejiang, China. Zhejiang Huahai describes itself as a leader in drug development and the manufacture of active pharmaceutical ingredients, which have been exported in substantial quantities to the United States for use in drugs sold to individuals in the United States and paid for by Plaintiff and similarly situated payers. Zhejiang Huahai claims that it is in strict compliance with current Good Manufacturing Processes ("cGMP"), In 2017, Zhejiang Huahai claimed it has sales of $50 million.[6] Zhejiang Huahai has engaged in substantial and continuous business in the United

[5] *See* U.S. Food and Drug Administration spreadsheet available at https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf

[6] Ben Hirschler, *China Heart Drug Sold Globally May Have Had Impurity Since 2012*, CNBC (July 17, 2018, 1:36 PM), https://www.cnbc.com/2018/07/17/reuters-america-china-heart-drug-sold-globally-may-have-had-impurity-since-2012.html.

States, including in the District, by applying for and receiving FDA approval to import into the United States active pharmaceutical ingredients used to manufacture Valsartan, by establishing Huahai U.S. is its American division operating from the same address as Prinston, and through its ownership of Solco and Prinston, both of which maintain a principal place of business in the District. Defendant Zhejiang Huahai manufactured NDEA-contaminated Irbesartan API and NDMA-contaminated Valsartan for Defendant generic manufacturers to sell to insureds in the United States.

## REGULATORY AND ECONOMIC BACKGROUND

42. Under federal law, pharmaceutical drugs must be manufactured in accordance with cGMP. cGMP compliance ensures that a product will meet safety, quality, purity, identity, and strength standards.[7]

43. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" and may not be distributed or sold in the United States.[8]

44. cGMP includes a prohibition on manufacturers contracting out prescription drug manufacturing without sufficiently overseeing and ensuring the continued quality of its contractor's facilities.[9] In fact, the FDA requires a "quality control unit" to independently test drug product manufactured by a contract manufacturer.[10]

[7] 21 U.S.C. § 351(a)(2)(B).

[8] 21 U.S.C. §§ 331(a), 351 (a)(2)(B).

[9] 21 U.S.C. § 351(j).

[10] 21 C.F.R. § 211.22(a).

45. The FDA requires manufacturers to test in-process materials for "identity, strength, quality, and purity as appropriate . . . during the production process, e.g., at commencement or completion of significant phases of after storage for long periods.[11]

46. The FDA is authorized to perform inspections and may issue a Form 483 letter to firm management when an investigator "observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act ("FDCA") and related Acts . . . Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device, or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."[12]

47. As with cGMP, there are various regulations governing the manufacture of generic drug products specifically. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book. A generic drug manufacturer must submit an Abbreviated New Drug Application ("ANDA") to the FDA for approval to be listed an AB-rated substitute, or generic, for a reference listed drug ("RLD").

48. When the FDA approves an ANDA, that generic drug receives an "AB" rating from the FDA, signifying it is therapeutically equivalent to the brand-name drug. Therapeutic equivalence indicates that the generic is both pharmaceutically equivalent (same dosage form, route of administration, identical strength or concentration) and bioequivalent (no significant

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[11] 21 C.F.R. § 211.110(c).

[12] *FDA Form 483 Frequently Asked Questions*, FDA, https://www.fda.gov/ICECI/Inspections/ucm256377.htm (last visited Oct. 24, 2018).

difference in the rate and extent of absorption of the active pharmaceutical ingredient) to the brand-name drug.

49. Once approved, a manufacturer may only produce their FDA-approved drug product according to the process and specifications contained in their ANDA. Any changes to the process must be filed and approved with the FDA. There are various tools a manufacturer may use to amend their ANDA, including a Prior Approval Supplement ("PAS"), Supplement-Changes Being Effected in 30 days ("CBE-30"), Supplement- Changes Being Effected ("CBE"), or an Annual Report.[13]

50. The United States prescription drug product economic relationship fundamentally departs from basic economic norms. For most consumer products, the person responsible for paying is the person selecting and using the product.

51. Here, health insurers and patients pay for the prescription drug that a patient is prescribed. The overwhelming majority of the cost of prescription drugs is paid for by TPPs. Generally, TPPs pays the majority of the price of the prescription drug and their member pays a small cost-sharing obligation. Defendants are well aware of this economic relationship and understand that the vast majority of the price charged was borne by TPPs, like Plaintiff and the Class it brings this action on behalf of.

## CLASS ACTION ALLEGATIONS

52. Plaintiff brings this action pursuant to Fed.R.Civ.P. 23(a) and 23(b)(1), 23(b)(2), and 23(b)(3) on behalf of itself and all others similarly situated, as members of a class (the "Third-Party Payer Class" or the "Class") defined as follows:

[13] 21 U.S.C. § 356; 21 C.F.R. § 314.70.

All insurance providers and other third-party payers, excluding governmental entities and any Defendant or entity controlled by any Defendant, that paid all or part of the expense for Valsartan, Irbesartan, Losartan, Valsartan-containing products, Irbesartan-containing products, and/or Losartan-containing products, contaminated with NDMA or NDEA identified on Exhibit A, the FDA's list of recalled NDMA-contaminated Valsartan, NDEA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan, or any updated list of NDMA-contaminated Valsartan, NDEA-contaminated Valsartan, NDEA-contaminated Irbesartan, or NDEA-contaminated Losartan released by FDA through the date of trial.

53. The Third-Party Payer Class is so numerous that joinder of all its members is impractical. There are thousands of TPPs in the Class. TPPs include without limitation traditional insurance companies providing health and prescription drug coverage, health maintenance organizations, various forms of ERISA plans, self-insured employers, and union benefit funds.

54. There are questions of law and fact common to the Third-Party Payer Class which predominate over questions affecting only individual members of the Class, including but not limited to the following:

a. whether NDMA or NDEA-contaminated Valsartan, Irbesartan, and/or Losartan were worthless;

b. whether Third-Party Payers paid to replace Valsartan, Irbesartan and/or Losartan discarded because of the recall and if so in what amount;

c. whether Defendants' conduct constitutes a breach of express and implied warranties;

d. whether Defendants' conduct constitutes unjust enrichment;

e. whether the Class is entitled to damages, and if so, the amount of damages.

55. The claims of the Plaintiff are typical of the claims of the Third-Party Payer Class. Like other third-party payers, Plaintiff provided prescription drug coverage to its

members and paid for the contaminated drugs and, after the recall, it paid to replace contaminated ARBs with substitute safe drugs or for other treatment options.

56. The representative Plaintiff, by its counsel, will fairly and adequately assert and protect the interests of all members of the Class in that said counsel have experience in prosecuting class actions on behalf of third-party payers and have specific experience and knowledge concerning the substantive legal issues likely to arise in this litigation.

57. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

58. Common issues predominate over individualized issues in this case.

59. Class certification is appropriate under Fed.R.Civ.P. 23(b)(1)(A) because the prosecution of separate actions by individual Class members could create a risk of (A) inconsistent or varying adjudications with respect to individual members of the Class; (B) adjudications with respect to individual Class members which would, as a practical matter, be dispositive of the interests of all members of the Third-Party Payer Class, or which would substantially impede or impair their ability to protect their interests.

## FACTS RELEVANT TO ALL CAUSES OF ACTION

### A. Valsartan, Irbesartan, and Losartan are widely-prescribed generic high blood pressure drugs.

60. Valsartan is a common off-patent[14] angiotensin-II-receptor antagonist used to treat hypertension (high blood pressure), recent heart attack, and heart failure. Hypertension is a common condition effecting 75 million Americans where the pressure of blood in a blood vessel

[14] The U.S. patents for valsartan and valsartan/hydrochlorothiazide expired in September 2012.

is higher than it should be.[15] Untreated, hypertension can damage blood vessels in the brain, heart, and kidneys, resulting in increased risk of stroke, heart failure, or kidney failure.

61. In 2016, 14 million prescriptions were written for Valsartan or a drug that includes it, and demand for the drug has not significantly changed since then.[16]

62. Valsartan is available on its own or in combination with other active substances. It is produced in 40, 80, 160, and 320 milligram tablet dosages.

63. The United States market for Valsartan is in the hundreds of millions, if not billions, of dollars per year. Prior to going off-patent, Valsartan was marketed by Novartis AG under the brand name Diovan® and produced $2.333 billion of net sales in the United States in 2011.[17] In 2014, brand Diovan had annual sales of $1.8 billion in the United States.[18] In 2017, Diovan produced $957 million of net sales in the United States.[19] Generic valsartan presumably accounts for much of the difference in sales between 2011 and 2017. The proportion of patients taking Valsartan/Diovan has not changed[20], so the total market value of valsartan-containing drugs likely remains more than $2 billion per year.

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[15] *High Blood Pressure*, CENTERS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/bloodpressure/index.htm (last updated July 18, 2018).

[16] National Center for Health Statistics. "Health, United States, 2016: With Chartbook on Long-term Trends in Health." 2017; Fryar *et al.* "Hypertension prevalence and control among adults: United States, 2015–2016." NCHS data brief, No. 289. Hyattsville, MD: National Center for Health Statistics. 2017.

[17] Novartis Annual Report 2011, p. 164.

[18] *Teva Launches Generic Diovan® in the United States*, TEVA PHARMACEUTICAL INDUSTRIES LTD., https://www.tevapharm.com/news/teva_launches_generic_diovan_in_the_united_states_01_15.aspx (last visited Oct. 24, 2018).

[19] Novartis Annual Report 2017, p. 206.

[20] National Center for Health Statistics. "Health, United States, 2016: With Chartbook on Long-term Trends in Health." 2017; Fryar *et al.* "Hypertension prevalence and control among adults: United States, 2015–2016." NCHS data brief, No. 289. Hyattsville, MD: National Center for Health Statistics. 2017.

64. Valsartan is available as a generic drug manufactured, labeled, or sold by a variety of manufacturers and repackagers in the United States, including Defendant generic drug manufacturers.

65. Irbesartan is an angiotensin receptor blocker used to treat hypertension. It is available as a generic drug manufactured, labeled, or sold by a variety of manufacturers and repackagers in the United States, including Defendant generic drug manufacturers.

66. Losartan is an angiotensin receptor blocker used to treat hypertension. It is also used to reduce the risk of stroke in patients with high blood pressure and an enlarged heart. It is available as a generic drug manufactured, labeled, or sold by a variety of manufacturers and repackagers in the United States, including Defendant generic drug manufacturers.

67. At all relevant times, Defendant generic drug manufacturers used contract manufacturer, Hetero and Zhejiang Huahai, to manufacture their Valsartan, Irbesartan, and Losartan products. Defendant generic manufacturers then sold Valsartan, Irbesartan, and Losartan containing an active pharmaceutical ingredient (API) manufactured by either Hetero or Zhejiang Huahai.

68. An API is: (A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended (i) to be used as a component of a drug; and (ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or (B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

69. Defendant generic manufacturers willfully and negligently ignored warnings regarding the operating standards at the Zhejiang Huahai facility and continued to permit Zhejiang Huahai to manufacture the Valsartan and Irbesartan API that they would sell in the United States.

**B. The Valsartan, Irbesartan, and Losartan manufactured, labeled, or sold by Defendants contained an active pharmaceutical ingredient tainted with carcinogenic NDMA and/or NDEA manufactured in China and/or India.**

70. Zhejiang Huahai serves as a contract manufacturer of Defendants' Valsartan and Irbesartan. Defendants are, therefore, obligated to monitor and quality control the facilities Zhejiang Huahai uses to manufacture Valsartan and Irbesartan.

71. Zhejiang Huahai has a long history of deviated from cGMP requirements. In March 2007, an FDA inspection of Zhejiang Huahai's Linhai City, Chuannan plant revealed "deviations from current good manufacturing processes."

72. In its May 2017 inspection, FDA again found that Zhejiang Huahai's Chuannan facility failed to conform to cGMP. Zhejiang Huahai routinely tested out of specification samples until tests revealed a within specification result. Zhejiang Huahai would typically "invalidat[e] out-of-specification results [without] adequate scientific justification." FDA also found that "impurities" were not consistently documented and data was manipulated to intentionally conceal and/or disregard the presence of harmful impurities in the prescription drug products. Plaintiff was not informed of these findings.

73. The FDA's May 2017 inspection further observed that "[f]acilities and equipment are not maintained to ensure quality attributes of drug product." These manufacturing problems included deteriorating equipment such that "the missing portions could not be accounted for,"

rusted equipment, "particulate matter and paint falling," and "black metallic particles" in the drug batch.

74. According to the European Medical Agency, NDMA and NDEA were formed as a byproduct after Zhejiang Huahai changed its Valsartan and Irbesartan manufacturing processes starting in 2012. This change involved reusing certain materials. The process change also caused specific chemicals to react forming NDMA. Hetero Labs made similar process changes to its production of Valsartan and Losartan that resulted in the introduction of NDMA and NDEA into those products.

75. NDMA and NDEA are not FDA-approved ingredients for Valsartan. Defendants' products do not identify NDMA or NDEA as either an active ingredient or an excipient of their Valsartan, Irbesartan or Losartan. Zhejiang Huahai and Hetero introduced NDMA and NDEA into the API it sold to Defendants for use in Valsartan, Irbesartan, and Losartan marketed, labeled, and sold in the United States.

76. Had Defendants fulfilled their quality assurance obligation, and/or complied with cGMP, Defendants would have identified NDMA contamination in their Valsartan products immediately and *should* have withdrawn affected lots of Valsartan from the market, so that Plaintiffs and consumers alike would not have purchased contaminated drug products.

77. However, facts indicate that Defendants and Zhejiang Huahai had actual knowledge of NDMA contamination in their Valsartan and Irbesartan products, and not only did they fail to take corrective action, but they attempted to conceal and destroy evidence of cancer-causing contamination in hypertension prescription drugs that United States patients consumed

between 2012 and December 2019 and would have consumed had the FDA not issued a recall in July 2018, and additional subsequent recalls thereafter.

78. The FDA's May 2017 Zhejiang Huahai inspection results suggest that Zhejiang Huahai and Defendants were aware of impurities in the drugs Zhejiang Huahai was manufacturing in China, including Valsartan and Irbesartan. Efforts to manipulate, distort and disregard data suggesting impurities is an express effort to conceal evidence and willfully and intentionally introduce adulterated Valsartan and Irbesartan into the U.S. market to be ingested by patients suffering from hypertension.

79. For at least 6 years, Defendants introduced their generic Valsartan and Irbesartan into the U.S. market representing that it was an FDA-approved therapeutically equivalent generic for Diovan. Further, Defendant Solco states in its website that it produces products "which are identical to the branded medication." This is demonstrably false. Brand Diovan does not contain NDMA. Defendant Teva similarly states on its website that "[t]he generic product's…purity profile is similar, and it is found to be bioequivalent." Diovan and Teva's generic valsartan produced by Zhejiang Huahai do not share a similar purity profile. Teva's website also proclaims, falsely, that it impeccably adheres to cGMP.

80. The World Health Organization ("WHO") concluded that NDMA "is clearly carcinogenic."[21] The WHO reports that "[t]here is overwhelming evidence that NDMA is mutagenic and clastogenic" and that it "has been consistently shown to be a potent carcinogen in all experimental species studied." The WHO concludes, "NDMA is a genotoxic carcinogen, and exposure should be reduced to the extent possible."

[21] Liteplo *et al.* "Concise International Chemical Assessment Document 38: *N*-Nitrosodimethylamine." World Health Organization. 2002. p. 4.

81. According to the WHO, "NDMA belongs to a class of chemicals known as *N*-nitroso compounds, characterized by the *N*nitroso functional group (–N–N=O), and to the family of nitrosamines, which, in addition, possess an amine function (–NR2, where R is H or an alkyl group). NDMA is also known as dimethylnitrosamine, dimethylnitrosoamine, *N*,*N*-dimethylnitrosamine, *N*-methyl-*N*nitrosomethanamine, *N*-nitroso-*N*,*N*-dimethylamine, DMN, and DMNA."

82. According to the United States Environmental Protection Agency ("EPA"), NDMA is a "semivolatile organic chemical" that is a contaminant due to its "carcinogenicity and toxicity."[22]

83. NDEA is a pale yellow liquid used as an additive to gasoline and lubricants, and as a stabilizer in plastic. The WHO found that NDEA is a carcinogen. The New Jersey Department of Health lists NDEA on the Special Health Hazard Substance List.

84. The FDA concluded that NDEA and NDMA have the potential to cause harm at very low levels and that it has elevated the risk of cancer among patients who ingested NDMA and NDEA-contaminated ARBs. FDA scientists estimate that if 8,000 people took the highest daily valsartan dose (320 mg) that contained NDMA, for four years (the time FDA believes the affected products were on the U.S. market), there may be one additional case of cancer beyond the average cancer rate among those 8,000 Americans.

85. The FDA recognizes NDMA contamination as a "genotoxic" impurity, which means that it is able to damage genetic material in cells such as DNA.

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[22] *Technical Fact Sheet - N-Nitroso-dimethylamine (NDMA)*, EPA (Nov. 2017) https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

86. Defendants did not disclose to Plaintiff, the general public, or regulators (including the FDA) that the Valsartan, Irbesartan, and Losartan they sold was tainted with NDMA.

87. Plaintiff paid for Valsartan, Irbesartan, and Losartan tainted with NDMA and/or NDEA.

88. Plaintiff was unaware of that contamination at the time it paid for the drugs tainted with NDMA and/or NDEA manufactured, labeled, repackaged, or sold by Defendants.

89. Valsartan, Irbesartan, and Losartan tainted with NDMA and/or NDEA have no economic value in the marketplace and is worthless.

**C. The FDA Issues Recalls of Contaminated Valsartan, Irbesartan, and Losartan**

90. A U.S. manufacturer of Valsartan products, Prinston Pharmaceuticals Inc., contacted the FDA on June 19, 2018 about adulterated Valsartan API manufactured by Zhejiang Huahai.

91. The FDA's responsibilities include protecting the public health by assuring the safety, effectiveness, and security of drugs intended for human use.

92. It is the manufacturer's responsibility to understand and assess their manufacturing process, assess any changes to that process and, based on that assessment and understanding, ensure test methods utilized can detect impurities expected to develop during the manufacturing process. Zhejiang Huahai failed to meet this responsibility.

93. On July 13, 2018, the FDA announced a recall of numerous lots of NDMA-contaminated Valsartan sold by generic drug manufacturers and repackagers in the United States that fail to meet FDA safety standards. According to FDA:[23]

> "We have carefully assessed the valsartan-containing medications sold in the United States, and we've found that the valsartan sold by these specific companies does not meet our safety standards. This is why we've asked these companies to take immediate action to protect patients."

94. Under federal regulations, a "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. § 7.3(g).

95. On October 30, 2018, the FDA publicized the initial Irbesartan recall noting that it "contain[s] N-Nitrosodiethylamine (NDEA), a known animal and suspected human carcinogen."

96. The FDA issued its initial Losartan recall on November 9, 2018, finding that "Sandoz's product was made using an active pharmaceutical ingredient (API) that has tested positive for NDEA. The API was manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd."

97. The FDA has repeatedly expanded the scope of the recall. Its most current list of Valsartan, Irbesartan, and Losartan products subject to the recall is attached as **Exhibit A**.

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[23] *See* FDA News Release available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm. On July 6, 2018, twenty-two other countries' prescription drug regulatory agencies recalled valsartan that likely contained NDMA impurities. The recall involved 2,300 batches that were sent to Germany, Norway, Finland, Sweden, Hungary, the Netherlands, Austria, Ireland, Bulgaria, Italy, Spain, Portugal, Belgium, France, Poland, Croatia, Lithuania, Greece, Canada, Bosnia and Herzegovina, Bahrain, and Malta.

98. On July 16, 2018, the New York Times published an article summarizing the FDA's warning and advising patients that "[t]heir health care provider should be able to offer other treatment options, among them, another valsartan product that is not part of the recall."[24]

99. From July 23 to August 3, 2018, FDA conducted inspections of Zhejiang Huahai's Chinese facilities to investigate the root cause of the NDMA in the Valsartan API it produced.

100. On August 3, 2018, FDA issued a Form 483[25] letter regarding Zhejiang Huahai's quality management systems, validation procedures, manufacturing processes, and product specifications. The Form 483 noted, among other things, that (1) the control system to evaluate changes that may affect the production and control of intermediates or API is not adequate, (2) Zhejiang Huahai initiated validation on a commercial scale without conducting a formal risk assessment to evaluate the potential impact of changes to its already validated manufacturing process on the quality of intermediates and API, (3) Zhejiang Huahai's "manufacturing processes are not always capable of consistently producing final products meeting all product quality specifications."

101. The Form 483 also documents 17 instances of "reprocessing" of out-of-specification samples that Zhejiang Huahai attributed to "lab related errors", "production errors", and a "combination of lab and production errors."

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[24] Sheila Kaplan, *Blood Pressure Medicine is Recalled*, The N.Y. Times (July 16, 2018), https://www.nytimes.com/2018/07/16/health/fda-blood-pressure-valsartan.html.

[25] An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the FDCA and related Acts.

102. On September 13, 2018, the FDA provided an additional update writing that it learned that "[Zhejiang Huahai] found NDEA in several batches of its valsartan API." NDEA is N-Nitrosodiethylamine, a known animal and suspected human carcinogen.

103. On September 28, 2018, as a result of information learned during inspections, FDA placed Zhejiang Huahai on Import Alert 66-40 to stop all of the API and finished drugs made using its API from legally entering the U.S. The Import Alert applies to articles manufactured at Zhejiang Huahai, located at Coastal Industrial Zone, Chuannan No. 1 Branch No. 9, Donghai Fifth Avenue, Linhai, Taizhou Zhejiang.

104. On November 29, 2018, FDA also issued Zhejiang Huahai a warning letter outlining several manufacturing violations, including failures of impurity control, change control and cross contamination from one manufacturing process line to another. FDA also determined that that Zhejiang Huahai significantly deviated from cGMP for API.

105. FDA's inspections revealed systemic problems of supervision that could have created the conditions for quality issues, such as the NDMA contamination, to arise.

106. According to the FDA, the NDMA-related recall affects more than 40% of the U.S. market of Valsartan-containing drugs.

107. According to the FDA, Valsartan, Irbesartan, and Losartan contaminated with NDMA and/or NDEA has caused an elevated cancer risk in the affected population.

108. According to the FDA's review of records from manufacturers, the impurity may have been in Valsartan manufactured over the last four years, but possibly as far back as

November 2011 when Zhejiang Huahai approved a Valsartan API process change that included the use of a solvent.[26]

109. The recall was meant to quickly remove unsafe products from the market, but FDA advised patients taking NDMA and NDEA-contaminated ARBs to "continue taking their current medicine until their doctor or pharmacist provides a replacement or a different treatment option"[27] because of the risks associated with untreated high blood pressure.

110. In response to the recall, pharmacies and health care providers throughout the United States contacted affected patients to advise them of the recall and to recommend that they contact their doctors to request a replacement or an alternative treatment option.

111. Because of the seriousness of the impurity—unsafe levels of a carcinogen—substantially all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. The NDMA and NDEA-contaminated Valsartan, Irbesartan, and Losartan had no use and was discarded.

112. TPPs, including Plaintiff, paid to replace NDMA and NDEA-contaminated Valsartan, Irbesartan, and Losartan with replacement drugs without being reimbursed for the cost of the recalled (discarded) drugs. TPPs, including Plaintiff, incurred additional costs associated with the recall, including doctor's visits to switch patients to new drugs and discuss patient concerns about exposure to a carcinogen. Defendants have failed and refused to refund TPPs for unused drugs or for the costs of switching patients to substitute drugs or other treatment options.

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[26] Spear, Lisa. "Heart Drug Valsartan May Have Been Contaminated with Cancer-Linked Impurity Since 2012." *Newsweek*. 17 July 2018. <https://www.newsweek.com/heart-drug-valsartan-may-have-been-contaminated-cancer-linked-impurity-2012-1029234> (citing European Medicines Agency, "Update on review of valsartan medicines following detection of impurity in active substance")

[27] FDA updates on valsartan recalls (August 20, 2018). Emphasis added. <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>

113. NDMA and/or NDEA-contaminated Valsartan, Irbesartan, and Losartan are worthless and should never have been marketed or sold to the public, yet TPPs paid for these worthless products years.

**D. Third-party payers paid tens of millions of dollars for Valsartan.**

114. Plaintiff provided and continues to provide thousands of enrolled employees and dependents with a prescription medication benefit that fully or partially pays for the cost of purchasing Valsartan, Irbesartan, and Losartan.

115. The prescription drug plan of Plaintiff and similarly situated Class Members permitted members to purchase prescription drugs and medications at participating pharmacies in exchange for a fixed co-payment or a percentage of the drug's price. The remainder of the cost of the drug is borne by Plaintiff and similarly situated Class Members. Plaintiff paid thousands of dollars for the recalled drugs manufactured and sold by Defendant generic drug manufacturers and repackagers containing NDMA and/or NDEA-contaminated API sold by Hetero and/or Zhejiang Huahai. Plaintiff also paid thousands of dollars to replace the recalled drugs with substitute drugs or other treatment thereby effectively paying twice for drugs intended for the same purpose over the same time period.

116. Numerous other health care insurers and entities contractually or otherwise obligated to pay for prescription drugs on behalf of third-parties offered prescription drug coverage similar to Plaintiff throughout the United States and paid, collectively, tens of millions of dollars for their members' purchases of the contaminated drugs.

117. By virtue of their payments for Valsartan, Irbesartan, and Losartan made on behalf of their members, Plaintiffs and the Class have contractual and equitable rights in subrogation through which they have become subrogated to rights of recovery possessed by their

respective members with respect to their purchases of contaminated Valsartan, Irbesartan, and/or Losartan.

118. By virtue of their payments for Valsartan, Irbesartan, and Losartan, Plaintiff and the Class bore some or all of the expenses caused by Defendants' wrongful conduct as alleged herein. Plaintiffs and the Class therefore also possess direct claims, and seek recovery in their own right, against Defendants.

## CAUSES OF ACTION

### Count I
### Breach of Implied Warranty of Merchantability and Fitness

119. The allegations in the preceding paragraphs of this Complaint are realleged and incorporated by reference as though fully set forth herein.

120. Defendants made an implied warranty of merchantability and fitness in connection with the sale of Valsartan, Irbesartan, and Losartan.

121. Valsartan, Irbesartan, and Losartan contaminated with a potent human carcinogen was not merchantable or fit for its intended use at the time of sale and Defendants therefore breached their implied warranties.

122. Plaintiff and the Class have suffered damage caused by the Defendants' breach of the warranty of merchantability and fitness because they paid for NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and/or NDEA-contaminated Losartan and also because they paid to replace these products with alternative safe drugs or other treatment options.

123. Plaintiff and the Class have also suffered damages because the contaminated drug products were worthless at the time of sale.

**Count II**
**Strict Liability**

124. The allegations in the preceding paragraphs of this Complaint are realleged and incorporated by reference as though fully set forth herein.

125. The NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan were defectively manufactured because it should not have contained NDMA and/or NDEA, the presence of elevated levels of NDMA and/or NDEA violated federal law, and the presence of NDMA and/or NDEA put consumers at an elevated risk of cancer.

126. The contaminated drug products were expected to and did reach consumers without substantial change or adjustment.

127. Defendants knew or should have known of manufacturing defect and the risk of serious bodily injury that exceeded the benefits, of which known are known, of contaminating Valsartan, Irbesartan, and Losartan with NDMA or NDEA.

128. NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan present an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

129. NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan are inherently dangerous for their intended uses due to manufacturing defects and the presence of NDMA and/or NDEA. Defendants are, therefore, strictly liable.

130. As a proximate result of the manufacturing defect for which Defendants are responsible, which caused the presence of NDMA and/or in Valsartan, Irbesartan, and Losartan

and the failure to detect the presence of that toxin, Plaintiff and the Class have suffered economic losses.

**COUNT III**
**Violation of New Jersey's Consumer Fraud Act**

131. The allegations in the preceding paragraphs of this Complaint are realleged and incorporated by reference as though fully set forth herein.

132. Plaintiff brings this claim individually and on behalf of the Class under New Jersey's Consumer Fraud Act ("NJCFA").

133. Plaintiff and other members of the Class are "persons" within the meaning of N.J.S.A. 56:8-1(d).

134. Defendants' conduct alleged herein constitutes a "sale" within the meaning of N.J.S.A. 56:8-1(e).

135. The NJCFA declares unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby[.]" N.J.S.A. 56:8-2.

136. Defendants have engaged in unfair, unlawful and deceptive acts in trade and commerce which have the capacity and tendency to deceive and, in fact, did deceive Plaintiff and the Class, and damaged Plaintiff and the Class.

137. Defendants affirmatively misrepresented (and/or wrongfully concealed and omitted) that the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan were therapeutically equivalent to the brand name drugs that they are AB-rated to and/or was manufactured in compliance with FDA good manufacturing practices and/or was not adulterated. In fact, Defendants' Valsartan, Irbesartan, and Losartan products were contaminated with NDMA and/or NDEA resulting in the drug as sold not being therapeutically equivalent to the brand-name drug for which it is AB-rated and not manufactured in compliance with FDA requirements and, in fact, constituting adulterated pharmaceuticals.

138. Defendants committed unlawful, deceptive, and unconscionable trade practices by marketing, selling, and otherwise placing into the stream of commerce NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan on the premise they were therapeutically equivalent to the brand-name drugs that they are AB-rated for, and/or manufactured in compliance with FDA requirements and/or were not adulterated.

139. Defendants wrongfully concealed, suppressed, and omitted to disclose that the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan were not therapeutically equivalent to the brand-name drug that they are AB-rated to and/or not manufactured in compliance with FDA requirements and/or was, in fact, adulterated.

140. Defendant's misrepresentations and omissions had the capacity to mislead Plaintiff and the Class into believing that the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan (i) was therapeutically equivalent to the brand-name drug that they are AB-rated to, (ii) was manufactured in accordance with FDA

requirements and/or (iii) was not adulterated and was legal to sell in the United States, when the opposite was true.

141. Had Defendants not made misrepresentations or not omitted such facts, the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan would not have been available to Plaintiff and the Class because, among other reasons, it would have been illegal for Defendants to sell the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan into the United States and import the API used to manufacture the contaminated Valsartan, Irbesartan, and Losartan. Plaintiff and the Class suffered ascertainable loss as a result.

142. Because of Defendants' unlawful, deceptive, unfair, and unconscionable trade practices, Plaintiff and the Class have suffered injury and damages – an ascertainable loss – in an amount to be determined at trial. Pursuant to the NJCFA, this Court has the power to enjoin Defendants' conduct.

143. The NJCFA prohibits deceptive acts and practices in the sale of products, with respect to the sale of NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan .

144. Plaintiff and the Class Members are "consumers," as defined under the NJCFA.

145. Defendants' conduct as alleged herein occurred in the course of "trade or commerce," as defined in the NJCFA.

146. Defendants misrepresented the characteristics of the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan, the ingredients in the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated

Losartan, the uses or benefits of the drugs; that the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan were safe for human consumption; that the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan were safe and effective; and that the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan was not adulterated.

147. In fact, the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan (a) did not have the characteristics, ingredients, uses or benefits represented, (b) was not safe for human consumption, (c) contained NDMA and or NDEA, and (d) was adulterated. This offends public policy, has caused and continues to cause substantial injury to Plaintiff and the Class, and constitutes an unfair and deceptive trade practice.

148. Upon information and belief, and given the fact that Defendants were responsible for designing, supplying, manufacturing, distributing, and/or selling the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan to Plaintiff and the Class, Defendants knew, or should have known at all relevant times that the Valsartan, Irbesartan, and Losartan were adulterated because they contained NDMA and/or NDEA and were not safe for human consumption. Nonetheless, Defendants falsely represented that the drugs paid for by Plaintiff and the Class was safe for human consumption, when they were not.

149. Defendants' false representations were likely to deceive consumers, third-party payers and the public, including Plaintiff and the Class Members.

150. Defendants intended for consumers, including Plaintiff and the Class, to rely on their representations that the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan were safe for human consumption when choosing to purchase

the drug. Plaintiff and the Class Members reasonably relied on such representations in making their decision to purchase the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan.

151. As a direct and proximate result of Defendants' deceptive and unfair trade practices, Plaintiff and the Class suffered actual damages, including monetary losses for the purchase price of the NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan which was not safe for human consumption and was worthless, and incidental medical expenses related to the withdrawal of the drug from the marketplace.

152. Thus, Plaintiff and the Class have been aggrieved by Defendants' unfair and deceptive practices, in violation of the NJCFA.

153. Defendants' conduct violates the NJCFA and, pursuant to N.J.S.A 56:8-1, *et seq* Plaintiff and the Class Members are entitled to damages in an amount to be proven at trial, reasonable attorneys' fees, injunctive relief prohibiting Defendants' unfair and deceptive practices going forward, and any other penalties or awards that may be just and proper.

**COUNT IV**
**Negligence**

154. The allegations in the preceding paragraphs of this Complaint are realleged and incorporated by reference as though fully set forth herein.

155. Defendants have a duty not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, distribution, advertising, preparing for use, and warning of the risks and dangers of Valsartan, Irbesartan, and Losartan.

156. Defendants' acts constitute an adulteration, as defined by the FDA, and constitute a breach of duty subjecting Defendants to civil liability for all damages arising from parallel state law duties, under the theory of negligence per se. Plaintiff disclaims and expressly does not allege that Defendants were obligated to any duty in excess of or that deviates from the requirements imposed by the FDA.

157. As a proximate result of Defendants' negligence, which caused the presence of NDMA and/or NDEA in Valsartan, Irbesartan, and Losartan and the failure to detect these toxins, Plaintiff and the Class have suffered economic losses.

**Count V**
**Unjust Enrichment**

158. The allegations in the preceding paragraphs of this Complaint are realleged and incorporated by reference as though fully set forth herein.

159. Plaintiff and the Class paid for NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan, thereby conferring a benefit on Defendants. Defendants expected and intended to receive the benefit of those payments. Defendants' profits would have been reduced, but for their wrongful and unlawful conduct.

160. Defendants have accepted and unjustly retained the benefit of payments by Plaintiff and the Class to the detriment of Plaintiff and the Class. Defendants appreciated and had knowledge of such benefits conferred by Plaintiff.

161. Defendants' retention of the benefit violates fundamental principles of justice, equity, and good conscience because Defendants were paid for unsafe products that should not have been sold in the United States and had no value.

162. Defendants have been unjustly enriched, and as a result of their conduct, Plaintiff and the Class have been damaged and Defendants must disgorge their profits from the sale of NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan and pay restitution to Plaintiff and the Class in an amount deemed just and proper.

**PRAYER FOR RELIEF**

163. Plaintiff on behalf of itself and all others similarly situated, pray for relief and judgment in favor of itself and the Class as follows:

A. For an order certifying the proposed Class under the appropriate provisions of Fed.R.Civ.P.23, and appointing Plaintiff and its counsel to represent the Class and appointing Plaintiff as a representative for the Class and Plaintiff's undersigned counsel as lead counsel for the Class;

B. For actual, compensatory, and consequential damages;

C. For disgorgement of Defendants profits associated with the sale of NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan and restitution for Plaintiff's and the Class' expenses associated with the sale of NDMA-contaminated Valsartan, NDEA-contaminated Irbesartan, and NDEA-contaminated Losartan and the costs to them associated with the recall;

D. For all relief available under New Jersey's Consumer Fraud Act, including injunctive relief

E. For punitive or exemplary damages against Defendants;

F. For attorneys' fees;

G. For pre and post-judgment interest;

H. For costs of suit; and

I. For such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff and the Class demand a trial by jury on all issues so triable.

DATED: January 30, 2019

Respectfully submitted,

Maine Automobile Dealers Association, Inc. Insurance Trust

By their attorneys,

*/s/Uriel Rabinovitz*

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# EXHIBIT A

| Valsartan products under recall - Updated December 31, 2018 | | | | |
|---|---|---|---|---|
| Company | Product | NDC | Lot | Expiration |
| Teva Pharmaceuticals labeled as Major Pharmaceuticals | Valsartan 80mg Tablets | 0904-6594-61 | T01795 | 05/2019 |
| | | | T01807 | 05/2019 |
| | | | T01712 | 02/2019 |
| | | | T01625 | 02/2019 |
| | | | T01596 | 02/2019 |
| | | | T01500 | 02/2019 |
| | | | T01466 | 07/2018 |
| | | | T01270 | 07/2018 |
| | Valsartan 160mg Tablets | 0904-6595-61 | T01646 | 05/2019 |
| | | | T01788 | 05/2019 |
| | | | T01668 | 05/2019 |
| | | | T01524 | 02/2019 |
| | | | T01269 | 07/2018 |
| Prinston Pharmaceutical Inc. labeled as Solco Healthcare LLC. | Valsartan 40mg Tablets, 30 count bottle | 43547-367-03 | All lots | 07/2018 to 01/2020 |
| | Valsartan 80mg Tablets, 90 count bottle | 43547-368-09 | | |
| | Valsartan 160mg Tablets, 90 count bottle | 43547-369-09 | | |
| | Valsartan 320mg Tablets, 90 count bottle | 43547-370-09 | | |
| | Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle | 43547-311-09 | | |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle | 43547-312-09 | | |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle | 43547-313-09 | | |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle | 43547-314-09 | | |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle | 43547-315-09 | | |
| Teva Pharmaceuticals USA labeled as Actavis | Valsartan 40mg Tablets, 30 count bottle | 0591-2167-30 | 1196936A | 09/2018 |
| | | | 1238463A | 05/2019 |
| | | | 1270617A | 10/2019 |
| | Valsartan 40mg Tablets, 90 count bottle | 0591-2167-19 | 1196934M | 09/2018 |
| | | | 1238462M | 05/2019 |
| | | | 1268429A | 10/2019 |
| | Valsartan 80mg Tablets, 90 count bottle | 0591-2168-19 | 1175947M | 07/2018 |
| | | | 1175948M | 07/2018 |
| | | | 1177115A | 07/2018 |
| | | | 1219361A | 02/2019 |
| | | | 1240434M | 05/2019 |
| | | | 1250704M | 05/2019 |
| | Valsartan 80mg Tablets, 1000 count bottle | 0591-2168-10 | 1177114A | 07/2018 |
| | | | 1219360M | 02/2019 |
| | | | 1250706A | 05/2019 |
| | Valsartan 160mg Tablets, 90 count bottle | 0591-2169-19 | 1177880A | 07/2018 |
| | | | 1220831A | 02/2019 |
| | | | 1263941A | 08/2019 |
| | Valsartan 160mg Tablets, 1000 count bottle | 0591-2169-10 | 1175922M | 07/2018 |
| | | | 1220826M | 02/2019 |
| | | | 1236294M | 05/2019 |
| | | | 1240427M | 05/2019 |
| | | | 1270616A | 08/2019 |
| | Valsartan 320mg Tablets, 90 count bottle | 0591-2170-19 | 1208002A | 10/2018 |
| | | | 1247282M | 05/2019 |
| | | | 1263944M | 08/2019 |
| | Valsartan 320mg Tablets, 500 count bottle | 0591-2170-05 | 1208000M | 10/2018 |
| | | | 1208001M | 10/2018 |
| | | | 1240425A | 06/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle | 0591-2315-19 | 1191191M | 08/2018 |
| | | | 1191192M | 08/2018 |
| | | | 1191193M | 08/2018 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | 1191194M | 08/2018 |
| | | | 1191195M | 08/2018 |
| | | | 1238466M | 06/2019 |
| | | | 1238467M | 06/2019 |
| | | | 1253261M | 07/2019 |
| | | | 1256125M | 07/2019 |
| | | | 1277709M | 09/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle | 0591-2316-19 | 1191160M | 09/2018 |
| | | | 1191161M | 09/2018 |
| | | | 1191162A | 09/2018 |
| | | | 1219363M | 02/2019 |
| | | | 1219364M | 02/2019 |
| | | | 1219365A | 02/2019 |
| | | | 1225613A | 02/2019 |
| | | | 1233944M | 04/2019 |
| | | | 1233945M | 04/2019 |
| | | | 1253253M | 07/2019 |
| | | | 1253254M | 07/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle | 0591-2317-19 | 1191164M | 09/2018 |
| | | | 1191165M | 09/2018 |
| | | | 1191166M | 09/2018 |
| | | | 1191167A | 10/2018 |
| | | | 1225612M | 02/2019 |
| | | | 1250717M | 07/2019 |
| | | | 1256111M | 07/2019 |
| | | | 1288798M | 10/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle | 0591-2318-19 | 1191185M | 09/2018 |
| | | | 1191186M | 09/2018 |
| | | | 1225615M | 02/2019 |
| | | | 1233948M | 02/2019 |
| | | | 1250718M | 08/2019 |
| | | | 1253257M | 07/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle | 0591-2319-19 | 1191188M | 09/2018 |
| | | | 1191189M | 09/2018 |
| | | | 1191190M | 09/2018 |
| | | | 1199220M | 08/2018 |
| | | | 1217576M | 01/2019 |
| | | | 1217577M | 01/2019 |
| | | | 1217578M | 01/2019 |
| | | | 1220832M | 01/2019 |
| | | | 1220833M | 02/2019 |
| | | | 1247283M | 06/2019 |
| | | | 1247284M | 06/2019 |
| | | | 1247285M | 06/2019 |
| | | | 1247286M | 06/2019 |
| | | | 1247287A | 06/2019 |
| | | | 1280632M | 10/2019 |
| | | | 1280633M | 10/2019 |
| AvKARE (Teva/Actavis) | Valsartan and Hydrochlorthiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle | 42291-884-90 | 17349 | 08/2018 |
| | | | 18395 | 08/2018 |
| | | | 19221 | 06/2019 |
| | | | 20029 | 06/2019 |
| | | | 20158 | 07/2019 |
| | | | 20843 | 07/2019 |
| | | | 21411 | 09/2019 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle | 42291-885-90 | 17325 | 09/2018 |
| | | | 17856 | 09/2018 |
| | | | 18396 | 09/2018 |
| | | | 18702 | 02/2019 |
| | | | 19020 | 02/2019 |
| | | | 19222 | 02/2019 |
| | | | 20030 | 04/2019 |
| | | | 20381 | 04/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle | 42291-886-90 | 17780 | 09/2018 |
| | | | 18029 | 09/2018 |
| | | | 18398 | 09/2018 |
| | | | 18723 | 09/2018 |
| | | | 19017 | 02/2019 |
| | | | 19224 | 02/2019 |
| | | | 20032 | 08/2019 |
| | | | 20289 | 08/2019 |
| | | | 21076 | 08/2019 |
| | | | 21382 | 08/2019 |
| | Valsartan and Hydrochlorothizaide (HCTZ) 160mg/25mg Tablets, 90 count bottle | 42291-887-90 | 17307 | 09/2018 |
| | | | 17857 | 09/2018 |
| | | | 18397 | 09/2018 |
| | | | 18722 | 09/2018 |
| | | | 19016 | 10/2018 |
| | | | 19223 | 02/2019 |
| | | | 20031 | 07/2019 |
| | | | 20382 | 07/2019 |
| | | | 21281 | 07/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle | 42291-888-90 | 17308 | 09/2018 |
| | | | 18158 | 09/2018 |
| | | | 18539 | 01/2019 |
| | | | 19021 | 01/2019 |
| | | | 19225 | 01/2019 |
| | | | 20033 | 06/2019 |
| | | | 20290 | 06/2019 |
| | | | 20565 | 06/2019 |
| | | | 21369 | 10/2019 |
| RemedyRepack Inc. (Prinston/Solco) | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablet, 90 count bottle | 70518-0925-0 | B0383153-122917 | 12/2018 |
| | Valsartan and Hydrochlorothiazide 160mg/12.5mg Tablets, 90 count bottle | 70518-0607-0 | B0318652-070617 | 07/2018 |
| A-S Medication Solutions LLC (Teva/Actavis & Prinston/Solco) | Valsartan 80mg Tablets, 90 count bottle | 54569-6582-1 | 342B17019 | 09/2019 |
| | | | 342B17018 | 08/2019 |
| | | | 342B17004 | 02/2019 |
| | | | 342B17002 | 11/2018 |
| | Valsartan 80mg Tablets, 30 count bottle | 54569-6582-0 | 342B17003 | 11/2018 |
| | | | 342B17004 | 02/2019 |
| | Valsartan 160mg Tablets, 90 count bottle | 54569-6583-1 | 343B17056 | 08/2019 |
| | | | 343B17053 | 08/2019 |
| | | | 343B17024 | 03/2019 |
| | | | 343B17016 | 02/2019 |
| | Valsartan 160mg Tablets, 30 count bottle | 54569-6583-0 | 343B17019 | 02/2019 |
| | | | 343B17023 | 03/2019 |
| | | | 343B17056 | 08/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 30 count bottle | 54569-6480-0 | 1233944M | 04/2019 |
| | | | 1253253M | 07/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle | 54569-6480-1 | 1253253M | 07/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 30 count bottle | 54569-6488-0 | 1191188M | 09/2018 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | 1191189M | 09/2018 |
| | | | 1217576M | 01/2019 |
| | | | 1247283M | 06/2019 |
| | | | 1247285M | 06/2019 |
| Bryant Ranch Prepack Inc. (Teva/Actavis) | Valsartan 80mg Tablets, 28 count bottle | 63629-6922-4 | 111158 | 02/2019 |
| | Valsartan 80mg Tablets, 60 count bottle | 63629-6922-3 | 111158 | 02/2019 |
| | Valsartan 80mg Tablets, 90 count bottle | 63629-6922-2 | 111158 | 02/2019 |
| | Valsartan 320 mg Tablets, 28 count bottle | 63629-6905-3 | 114319 | 10/2018 |
| | | | 109004 | 12/2018 |
| | Valsartan 320mg Tablets, 30 count bottle | 63629-6905-1 | 114319 | 10/2018 |
| | | | 109004 | 12/2018 |
| | Valsartan 320mg Tablets, 90 count bottle | 63629-6905-2 | 114319 | 10/2018 |
| | | | 109004 | 12/2018 |
| | Valsartan 320mg Tablets, 90 count bottle | 71335-0567-2 | 120879 | 10/2019 |
| H J Harkins Company Inc. dba Pharma Pac (Prinston/Solco) | Valsartan 160mg Tablets, 90 count bottle | 76519-1158-9 | VSA000OV | 02/2019 |
| Northwind Pharmaceuticals (Teva/Actavis) | Valsartan 80mg Tablets, 30 count bottle | 51655-652-52 | UT48310002 | 10/2018 |
| | Valsartan 160mg Tablets, 30 count bottle | 51655-460-52 | UT48320002 | 07/2018 |
| | | | UT48320003 | 05/2019 |
| | Valsartan 320mg Tablets, 30 count bottle | 51655-654-52 | UT48100001 | 09/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets | 51655-950-52 | UTB23790003 | 02/2019 |
| Hetero Labs, Inc. labeled as Camber Pharmaceuticals, Inc. | Valsartan 40mg Tablets, 30 count bottle | 31722-745-30 | All lots | 07/2018 - 06/2020 |
| | Valsartan 80mg Tablets, 90 count bottle | 31722-746-90 | | |
| | Valsartan 160mg Tablets, 90 count bottle | 31722-747-90 | | |
| | Valsartan 320mg Tablets, 90 count bottle | 31722-748-90 | | |
| NuCare Pharmaceuticals Inc. (Prinston/Solco) | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle | 68071-4311-9 | U01779 | 04/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 30 count bottle | 68071-2119-3 | T11443 | 02/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 30 count bottle | 68071-4183-3 | T11577 | 06/2019 |
| RemedyRepack, Inc. (Hetero/Camber) | Valsartan 80mg Tablets , 90 count bottle | 61786-0791-19 | B0335344-081717 | 08/2018 |
| | | | B0363364-110917 | 11/2018 |
| | | | B0391225-012218 | 01/2019 |
| | | | B0408458-030618 | 03/2019 |
| | | | B0384871-010318 | 01/2019 |
| | | | B0436862-051518 | 05/2019 |
| | Valsartan 160mg Tablets, 90 count bottle | 61786-0792-19 | B0335344-081717 | 08/2018 |
| | | | B0363364-110917 | 11/2018 |
| | | | B0391225-012218 | 01/2019 |
| | | | B0408458-030618 | 03/2019 |
| | | | B0384871-010318 | 01/2019 |
| | | | B0436862-051518 | 05/2019 |
| | Valsartan 320mg Tablets, 90 count bottle | 61786-0793-19 | B0362988-110917 | 10/2018 |
| | | | B0432265-050318 | 05/2019 |
| | | | B0450321-061218 | 06/2019 |
| | | | B0450322-061218 | 05/2019 |
| | | | B0408652-030718 | 02/2019 |
| AvKARE (Hetero/Camber) | Valsartan 40mg Tablets | 50268-783-15 | All lots | 07/2018 - 06/2020 |
| | Valsartan 80mg Tablets | 50268-784-15 | | |
| | Valsartan 160mg Tablets | 50268-785-15 | | |
| | Valsartan 320mg Tablets | 50268-786-13 | | |
| Preferred Pharmaceuticals, Inc. (Hetero/Camber) | Valsartan 320mg Tablets, 90 count bottle | 68788-6882-9 | G2017F | 10/2018 |
| Torrent Pharmaceuticals Limited | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/320mg/25mg Tablets, 30 count bottle | 13668-325-30 | BBX2C007 | 08/2018 |
| | | | BBX2D001 | 12/2018 |
| | | | BBX2D002 | 12/2018 |
| | | | BBX2D003 | 03/2019 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | BBX2D004 | 03/2019 |
| | | | BBX2D005 | 03/2019 |
| | | | BBX2D006 | 03/2019 |
| | | | BBX2D007 | 03/2019 |
| | | | BBX2D008 | 03/2019 |
| | | | BBX2D009 | 03/2019 |
| | | | BBX2D010 | 04/2019 |
| | | | BBX2D011 | 04/2019 |
| | | | BBX2D012 | 05/2019 |
| | | | BBX2D013 | 05/2019 |
| | | | BBX2D014 | 08/2019 |
| | | | BBX2D015 | 10/2019 |
| | | | BBX2D016 | 10/2019 |
| | | | BBX2D017 | 10/2019 |
| | | | BBX2D018 | 10/2019 |
| | | | BBX2D019 | 10/2019 |
| | | | BBX2D020 | 10/2019 |
| | | | BBX2D021 | 10/2019 |
| | | | BBX2D022 | 10/2019 |
| | | | BBX2D023 | 10/2019 |
| | | | BBX2D024 | 11/2019 |
| | | | BBX2D025 | 11/2019 |
| | | | BBX2D026 | 11/2019 |
| | | | BBX2E001 | 01/2020 |
| | | | BBX2E002 | 01/2020 |
| | | | BBX2E003 | 01/2020 |
| | | | BBX2E004 | 01/2020 |
| | | | BBX2E005 | 01/2020 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/25mg Tablets, 30 count bottle | 13668-328-30 | BBX9D001 | 02/2019 |
| | | | BBX9D002 | 03/2019 |
| | | | BBX9D003 | 07/2019 |
| | | | BBX9D004 | 11/2019 |
| | | | BBX9E001 | 01/2020 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 5mg/160mg/12.5mg Tablets, 30 count bottle | 13668-326-30 | BBY1C002 | 09/2018 |
| | | | BBY1D001 | 05/2019 |
| | | | BBY1E001 | 12/2019 |
| | | | BBY1E002 | 03/2020 |
| | | | BBY1E003 | 03/2020 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/12.5mg Tablets, 30 count bottle | 13668-327-30 | BBY2D001 | 02/2019 |
| | | | BBY2D002 | 11/2019 |
| | | | BBY2E001 | 03/2020 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 5mg/160mg/25mg Tablets, 30 count bottle | 13668-329-30 | BBY4D001 | 04/2019 |
| | | | BBY4D002 | 04/2019 |
| | | | BBY4D003 | 06/2019 |
| | | | BBY4D004 | 11/2019 |
| | | | BBY4E001 | 01/2020 |
| | Amlodipine and Valsartan 5mg/160mg Tablets, 30 count bottle | 13668-207-30 | BV53C004 | 08/2018 |
| | | | BV53C005 | 08/2018 |
| | | | BV53C006 | 11/2018 |
| | | | BV53D001 | 02/2019 |
| | | | BV53D002 | 02/2019 |
| | | | BV53D003 | 09/2019 |
| | | | BV53D004 | 10/2019 |
| | Amlodipine and Valsartan 10mg/160mg Tablets, 30 count bottle | 13668-206-30 | BV65C002 | 09/2018 |
| | | | BV65C003 | 10/2018 |
| | | | BV65C004 | 11/2018 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | BV65D001 | 08/2019 |
| | | | BV65D002 | 10/2019 |
| | Amlodipine and Valsartan 10mg/320mg Tablets, 30 count bottle | 13668-204-30 | BV77C001 | 10/2018 |
| | | | BV77C009 | 08/2018 |
| | | | BV77C010 | 08/2018 |
| | | | BV77D001 | 02/2019 |
| | | | BV77D002 | 02/2019 |
| | | | BV77D003 | 02/2019 |
| | | | BV77D004 | 02/2019 |
| | | | BV77D005 | 02/2019 |
| | | | BV77D006 | 02/2019 |
| | | | BV77D007 | 02/2019 |
| | | | BV77D008 | 05/2019 |
| | | | BV77D009 | 08/2019 |
| | | | BV77D010 | 09/2019 |
| | | | BV77D011 | 09/2019 |
| | | | BV77D012 | 09/2019 |
| | | | BV77D013 | 10/2019 |
| | Amlodipine and Valsartan 5mg/320mg Tablets, 30 count bottle | 13668-205-30 | BV84C006 | 08/2018 |
| | | | BV84C007 | 08/2018 |
| | | | BV84C008 | 08/2018 |
| | | | BV84C009 | 08/2018 |
| | | | BV84C011 | 10/2018 |
| | | | BV84D001 | 01/2019 |
| | | | BV84D002 | 01/2019 |
| | | | BV84D005 | 02/2019 |
| | | | BV84D006 | 02/2019 |
| | | | BV84D007 | 02/2019 |
| | | | BV84D008 | 05/2019 |
| | | | BV84D009 | 05/2019 |
| | | | BV84D010 | 10/2019 |
| | | | BV84E001 | 12/2019 |
| | Valsartan 80mg Tablets, 90 count bottle | 13668-068-90 | BV46C003 | 08/2018 |
| | | | BV46C006 | 08/2018 |
| | | | BV46C007 | 09/2018 |
| | | | BV46C008 | 10/2018 |
| | | | BV46C009 | 10/2018 |
| | | | BV46C010 | 10/2018 |
| | | | BV46C011 | 11/2018 |
| | | | BV46C012 | 11/2018 |
| | Valsartan 160mg Tablets, 90 count bottle | 13668-069-90 | BV47C003 | 08/2018 |
| | | | BV47C004 | 08/2018 |
| | | | BV47C005 | 09/2018 |
| | | | BV47C006 | 09/2018 |
| | | | BV47D001 | 12/2018 |
| | Valsartan 320mg Tablets, 90 count bottle | 13668-070-90 | BV48D001 | 12/2018 |
| | | | BV48D002 | 12/2018 |
| RemedyRepack, Inc. (Torrent) | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/320mg/25mg Tablets | 70518-1220-00 | B0476653-080218 | 08/2019 |
| | | | B0438903-052118 | 05/2019 |
| Mylan Pharmaceuticals | Amlodipine and Valsartan 5mg/160mg Tablets, 30 count bottle | 0378-1721-93 | 3066051 | 03/2019 |
| | Amlodipine and Valsartan 10mg/160mg Tablets, 30 count bottle | 0378-1722-93 | 3079500 | 01/2020 |
| | Amlodipine and Valsartan 10mg/320mg Tablets, 30 count bottle | 0378-1724-93 | 3061986 | 11/2018 |
| | | | 3079708 | 01/2020 |
| | | | 3079709 | 01/2020 |
| | | | 3077618 | 11/2019 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | Valsartan 40mg Tablets, 30 count bottle | 0378-5807-93 | 3061169 | 11/2018 |
| | Valsartan 80mg Tablets, 90 count bottle | 0378-5813-77 | 3063782 | 01/2019 |
| | Valsartan 160mg Tablets, 90 count bottle | 0378-5814-77 | 3071352 | 07/2019 |
| | Valsartan 320mg Tablets, 90 count bottle | 0378-5815-77 | 3081499 | 03/2020 |
| | | | 3080009 | 02/2020 |
| | | | 3080010 | 02/2020 |
| | | | 3079205 | 01/2020 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 500 count bottle | 0378-6325-05 | 3084886 | 02/2019 |
| | | | 3093804 | 12/2019 |
| Teva Pharmaceuticals USA Inc. | Amlodipine and Valsartan 5mg/160mg Tablets, 30 count bottle | 0093-7690-56 | 23X018 | 11/2018 |
| | | | 23X019 | 11/2018 |
| | | | 23X020 | 11/2018 |
| | | | 23X022 | 04/2019 |
| | | | 23X023 | 04/2019 |
| | Amlodipine and Valsartan 5mg/160mg Tablets, 90 count bottle | 0093-7690-98 | 23X017 | 11/2018 |
| | | | 23X018 | 11/2018 |
| | | | 23X019 | 11/2018 |
| | | | 23X023 | 04/2019 |
| | | | 23X024 | 04/2019 |
| | Amlodipine and Valsartan 10mg/160mg Tablets, 30 count bottle | 0093-7691-56 | 24X012 | 11/2018 |
| | | | 24X013 | 11/2018 |
| | Amlodipine and Valsartan 10mg/160mg Tablets, 90 count bottle | 0093-7691-98 | 24X012 | 11/2018 |
| | Amlodipine and Valsartan 5mg/320mg Tablets, 30 count bottle | 0093-7692-56 | 25X029 | 11/2018 |
| | | | 25X030 | 11/2018 |
| | | | 25X031 | 11/2018 |
| | | | 25X032 | 11/2018 |
| | | | 25X035 | 04/2019 |
| | | | 25X037 | 04/2019 |
| | Amlodipine and Valsartan 5mg/320mg Tablets, 90 count bottle | 0093-7692-98 | 25X028 | 11/2018 |
| | | | 25X029 | 11/2018 |
| | Amlodipine and Valsartan 10mg/320mg Tablets, 30 count bottle | 0093-7693-56 | 26X039 | 11/2018 |
| | | | 26X040 | 11/2018 |
| | | | 26X041 | 11/2018 |
| | | | 26X042 | 11/2018 |
| | | | 26X043 | 11/2018 |
| | | | 26X046 | 04/2019 |
| | | | 26X047 | 04/2019 |
| | | | 26X048 | 04/2019 |
| | | | 26X049 | 04/2019 |
| | | | 26X050 | 04/2019 |
| | | | 26X051 | 04/2019 |
| | Amlodipine and Valsartan 10mg/320mg Tablets, 90 count bottle | 0093-7693-98 | 26X036 | 11/2018 |
| | | | 26X038 | 11/2018 |
| | | | 26X039 | 11/2018 |
| | | | 26X044 | 04/2019 |
| | | | 26X045 | 04/2019 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 5mg/160mg/12.5mg Tablets, 30 count bottle | 0093-7807-56 | 18X010 | 02/2019 |
| | | | 18X011 | 02/2019 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 5mg/160mg/12.5mg Tablets, 90 count bottle | 0093-7807-98 | 18X010 | 02/2019 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/12.5mg Tablets, 30 count bottle | 0093-7810-56 | 20X006 | 11/2018 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/12.5mg Tablets, 90 count bottle | 0093-7810-98 | 20X006 | 11/2018 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/25mg Tablets, 30 count bottle | 0093-7038-56 | 21X006 | 11/2018 |
| | | | 21X007 | 02/2019 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/25mg Tablets, 90 count bottle | 0093-7038-98 | 21X006 | 11/2018 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/320mg/25mg Tablets, 30 count bottle | 0093-7809-56 | 22X045 | 02/2019 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | 22X046 | 02/2019 |
| | | | 22X047 | 02/2019 |
| | Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/320mg/25mg Tablets, 90 count bottle | 0093-7809-98 | 22X045 | 02/2019 |
| Mylan Pharmaceuticals | Amlodipine and Valsartan 5mg/160mg Tablets, 30 count bottle | 0378-1721-93 | 3064084 | 01/2019 |
| | | | 3069629 | 05/2019 |
| | | | 3073148 | 08/2019 |
| | | | 3073149 | 08/2019 |
| | | | 3076093 | 10/2019 |
| | | | 3077772 | 11/2019 |
| | Amlodipine and Valsartan 10mg/160mg Tablets, 30 count bottle | 0378-1722-93 | 3064085 | 01/2019 |
| | | | 3066063 | 03/2019 |
| | | | 3069638 | 05/2019 |
| | | | 3069639 | 06/2019 |
| | Amlodipine and Valsartan 5mg/320mg Tablets, 30 count bottle | 0378-1723-93 | 3064086 | 01/2019 |
| | | | 3066061 | 03/2019 |
| | | | 3066062 | 03/2019 |
| | | | 3073145 | 09/2019 |
| | | | 3073146 | 09/2019 |
| | | | 3073147 | 09/2019 |
| | | | 3076091 | 11/2019 |
| | | | 3077619 | 11/2019 |
| | | | 3082432 | 03/2020 |
| | Amlodipine and Valsartan 10mg/320mg Tablets, 30 count bottle | 0378-1724-93 | 3066064 | 03/2019 |
| | | | 3069645 | 06/2019 |
| | | | 3069646 | 06/2019 |
| | | | 3073142 | 09/2019 |
| | | | 3073143 | 09/2019 |
| | | | 3073144 | 09/2019 |
| | | | 3077617 | 11/2019 |
| | Valsartan 40mg Tablets, 30 count bottle | 0378-5807-93 | 3063780 | 01/2019 |
| | | | 3074879 | 10/2019 |
| | | | 3086684 | 06/2020 |
| | | | 3086687 | 06/2020 |
| | Valsartan 80mg Tablets, 90 count bottle | 0378-5813-77 | 3065445 | 02/2019 |
| | | | 3074880 | 10/2019 |
| | | | 3074883 | 10/2019 |
| | | | 3086688 | 06/2020 |
| | | | 3086689 | 06/2020 |
| | | | 3086710 | 06/2020 |
| | Valsartan 160mg Tablets, 90 count bottle | 0378-5814-77 | 3069019 | 05/2019 |
| | | | 3069020 | 05/2019 |
| | | | 3069021 | 05/2019 |
| | | | 3069022 | 05/2019 |
| | | | 3071354 | 07/2019 |
| | | | 3071355 | 07/2019 |
| | | | 3071357 | 07/2019 |
| | | | 3079023 | 01/2020 |
| | | | 3079027 | 01/2020 |
| | | | 3079028 | 01/2020 |
| | | | 3079029 | 01/2020 |
| | | | 3079996 | 02/2020 |
| | | | 3079997 | 02/2020 |
| | | | 3079998 | 02/2020 |
| | | | 3083635 | 04/2020 |
| | | | 3086715 | 06/2020 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | 3086716 | 07/2020 |
| | | | 3086717 | 07/2020 |
| | | | 3088623 | 08/2020 |
| | Valsartan 320mg Tablets, 90 count bottle | 0378-5815-77 | 3063783 | 01/2019 |
| | | | 3063784 | 01/2019 |
| | | | 3063785 | 01/2019 |
| | | | 3064092 | 01/2019 |
| | | | 3064093 | 01/2019 |
| | | | 3064094 | 01/2019 |
| | | | 3070349 | 06/2019 |
| | | | 3070350 | 06/2019 |
| | | | 3070351 | 06/2019 |
| | | | 3070352 | 06/2019 |
| | | | 3070353 | 06/2019 |
| | | | 3070354 | 06/2019 |
| | | | 3079030 | 01/2020 |
| | | | 3079031 | 01/2020 |
| | | | 3079032 | 01/2020 |
| | | | 3079033 | 01/2020 |
| | | | 3080011 | 02/2020 |
| | | | 3080224 | 02/2020 |
| | | | 3081498 | 03/2020 |
| | | | 3081500 | 03/2020 |
| | | | 3087126 | 07/2020 |
| | | | 3088476 | 08/2020 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 500 count bottle | 0378-6321-05 | 3084363 | 02/2019 |
| | | | 3093800 | 12/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle | 0378-6321-77 | 3084363 | 02/2019 |
| | | | 3084364 | 02/2019 |
| | | | 3093800 | 12/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 500 count bottle | 0378-6322-05 | 3084359 | 02/2019 |
| | | | 3084361 | 02/2019 |
| | | | 3093801 | 12/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle | 0378-6322-77 | 2008880 | 08/2020 |
| | | | 3084358 | 02/2019 |
| | | | 3084359 | 02/2019 |
| | | | 3093801 | 12/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 500 count bottle | 0378-6323-05 | 3084887 | 02/2019 |
| | | | 3084888 | 02/2019 |
| | | | 3093802 | 12/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle | 0378-6323-77 | 3084887 | 02/2019 |
| | | | 3093802 | 12/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 500 count bottle | 0378-6324-05 | 3084890 | 02/2019 |
| | | | 3093803 | 12/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle | 0378-6324-77 | 3084889 | 02/2019 |
| | | | 3093803 | 12/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 500 count bottle | 0378-6325-05 | 3084862 | 02/2019 |
| | | | 3084863 | 02/2019 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle | 0378-6325-77 | 3084860 | 02/2019 |
| | | | 3084861 | 02/2019 |
| | | | 3084862 | 02/2019 |
| | | | 3093804 | 12/2019 |
| Aurobindo Pharma USA, Inc. | Valsartan 320mg Tablets, 90 count bottle | 65862-573-90 | VUSD17008-A | 07/2019 |
| | | | VUSD17009-A | 09/2019 |
| | Amlodipine and Valsartan 5mg/160mg Tablets, 30 count bottle | 65862-737-30 | VESA17013-A | 10/2019 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | VESA17014-A | 10/2019 |
| | | | VESA18001-A | 12/2019 |
| | | | VESA18002-A | 12/2019 |
| | Amlodipine and Valsartan 5mg/320mg Tablets, 30 count bottle | 65862-738-30 | VMSA17012-A | 11/2019 |
| | | | VMSA17013-A | 11/2019 |
| | | | VMSA17014-A | 11/2019 |
| | | | VMSA17015-A | 11/2019 |
| | | | VMSA17016-A | 11/2019 |
| | | | VMSA17017-A | 11/2019 |
| | Amlodipine and Valsartan 10mg/160mg Tablets, 30 count bottle | 65862-739-30 | VFSA17008-A | 10/2019 |
| | | | VFSA17009-A | 10/2019 |
| | | | VFSA17010-A | 10/2019 |
| | | | VFSA18002-A | 01/2020 |
| | | | VFSA18003-A | 01/2020 |
| | | | VFSA18007-A | 03/2020 |
| | | | VFSA18008-A | 03/2020 |
| | Amlodipine and Valsartan 10mg/320mg Tablets, 30 count bottle | 65862-740-30 | VKSA17008-A | 05/2019 |
| | | | VKSA17014-A | 10/2019 |
| | | | VKSA17015-A | 10/2019 |
| | | | VKSA17016-A | 10/2019 |
| | | | VKSA17017-A | 10/2019 |
| | | | VKSA18001-A | 01/2020 |
| | | | VKSA18002-A | 01/2020 |
| | | | VKSA18004-A | 01/2020 |
| | | | VKSA18005-A | 03/2020 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle | 65862-547-90 | HVSA17011-A | 11/2020 |
| | | | HVSA17012-A | 11/2020 |
| | | | HVSA18001-A | 12/2020 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle | 65862-548-90 | HTSA17033-A | 10/2020 |
| | | | HTSA17034-A | 10/2020 |
| | | | HTSA17035-A | 10/2020 |
| | | | HTSA17036-A | 10/2020 |
| | | | HTSA17037-A | 10/2020 |
| | | | HTSA17039-A | 10/2020 |
| | | | HTSA17040-A | 10/2020 |
| | | | HTSA17041-A | 11/2020 |
| | | | HTSA17042-A | 11/2020 |
| | | | HTSA17043-A | 11/2020 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle | 65862-549-90 | HVSB17023-A | 08/2020 |
| | | | HVSB17036-A | 11/2020 |
| | | | HVSB17037-A | 11/2020 |
| | | | HVSB17038-A | 11/2020 |
| | | | HVSB17039-A | 11/2020 |
| | | | HVSB17040-B | 11/2020 |
| | | | HVSB18001-A | 12/2020 |
| | | | HVSB18002-A | 12/2020 |
| | | | HVSB18003-A | 12/2020 |
| | | | HVSB18004-A | 12/2020 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle | 65862-550-90 | HRSA17033-A | 10/2020 |
| | | | HRSA17034-A | 10/2020 |
| | | | HRSA17035-A | 10/2020 |
| | | | HRSA17036-A | 10/2020 |
| | | | HRSA17037-A | 10/2020 |
| | Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle | 65862-551-90 | HTSB17049-A | 08/2020 |
| | | | HTSB17054-A | 10/2020 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | HTSB17055-A | 10/2020 |
| | | | HTSB17056-A | 10/2020 |
| | | | HTSB17057-A | 10/2020 |
| | | | HTSB17058-A | 10/2020 |
| | | | HTSB17059-A | 10/2020 |
| | | | HTSB17060-A | 10/2020 |
| | | | HTSB17062-A | 10/2020 |
| | | | HTSB17063-A | 10/2020 |
| | | | HTSB17064-A | 10/2020 |
| | | | HTSB17065-A | 10/2020 |
| | | | HTSB17066-A | 10/2020 |
| | | | HTSB17067-A | 11/2020 |
| | | | HTSB17068-A | 11/2020 |
| | | | HTSB17069-A | 11/2020 |
| | | | HTSB18001-A | 12/2020 |
| | | | HTSB18002-A | 12/2020 |
| | | | HTSB18003-A | 12/2020 |
| | | | HTSB18004-A | 12/2020 |
| | | | HTSB18005-A | 12/2020 |
| | | | HTSB18006-A | 12/2020 |
| | | | HTSB18007-A | 12/2020 |
| | | | HTSB18029-A | 03/2021 |

## Losartan products under recall - Updated January 22, 2019

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| Sandoz Inc. | Losartan Potassium and Hydrochlorothiazide (HCTZ) 100mg/25mg Tablets, 1000 count bottle | 0781-5207-10 | JB8912 | 06/2020 |
| Torrent Pharmaceuticals Ltd. | Losartan Potassium 100mg Tablets, 30 count bottle | 13668-115-30 | BO31C016 | 04/2019 |
| | Losartan Potassium 100mg Tablets, 90 count bottle | 13668-115-90 | BO31C016 | 04/2019 |
| | Losartan Potassium 100mg Tablets, 1000 count bottle | 13668-115-10 | 4DK3C005 | 04/2019 |
| | | | 4DK3C004 | 04/2019 |
| | | | 4DU3C040 | 10/2019 |
| | | | 4DU3E049 | 05/2021 |
| | | | 4DU3E050 | 05/2021 |
| | Losartan Potassium 50mg Tablets, 30 count bottle | 13668-409-30 | 4L67C035 | 10/2019 |
| | Losartan Potassium 50mg Tablets, 90 count bottle | | 4L67C035 | 10/2019 |
| | | 13668-409-90 | 4L67C036 | 10/2019 |
| | Losartan Potassium 50mg Tablets, 1000 count bottle | 13668-409-10 | 4O50C005 | 11/2019 |
| | Losartan Potassium 25mg Tablets, 90 count bottle | 13668-113-90 | 4O49C013 | 09/2019 |
| | Losartan Potassium and Hydrochlorothiazide (HCTZ) 50mg/12.5mg Tablets, 90 count bottle | 13668-116-90 | BP02C008 | 03/2019 |
| | Losartan Potassium and Hydrochlorothiazide (HCTZ) 50mg/12.5mg Tablets, 1000 count bottle | 13668-116-10 | BEF7D006 | 03/2020 |
| | Losartan Potassium and Hydrochlorothiazide (HCTZ) 100mg/12.5mg Tablets, 90 count bottle | 13668-117-90 | BX35C020 | 05/2019 |
| | | | BX35C049 | 08/2019 |
| | Losartan Potassium and Hydrochlorothiazide (HCTZ) 100mg/12.5mg Tablets, 1000 count bottle | 13668-117-10 | BX35C022 | 05/2019 |
| | | | BX35C023 | 05/2019 |

# Irbesartan products under recall - Updated January 18, 2019

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| ScieGen Pharmaceuticals labeled as Westminster Pharmaceuticals | Irbesartan 75mg Tablets, 30 count bottle | 69367-119-01 | B160002A | 09/2019 |
| | Irbesartan 75mg Tablets, 90 count bottle | 69367-119-03 | B160002B | 09/2019 |
| | Irbesartan 150mg Tablets, 30 count bottle | 69367-120-01 | B161005A | 09/2019 |
| | | | C161002A | 02/2020 |
| | Irbesartan 150mg Tablets, 90 count bottle | 69367-120-03 | B161005B | 09/2019 |
| | | | C161002B | 02/2020 |
| | Irbesartan 300mg Tablets, 30 count bottle | 69367-121-01 | B162008A | 09/2019 |
| | | | C162002A | 02/2020 |
| | Irbesartan 300mg Tablets, 90 count bottle | 69367-121-03 | B162008B | 09/2019 |
| | | | C162002B | 02/2020 |
| ScieGen Pharmaceuticals labeled as GSMS Incorporated | Irbesartan 75mg Tablets, 90 count bottle | 60429-640-90 | B160003 | 09/2019 |
| | | | B160004 | 09/2019 |
| | Irbesartan 150mg Tablets, 30 count bottle | 60429-641-30 | GS019526 | 11/2019 |
| | | | GS020252 | 11/2019 |
| | | | GS020958 | 11/2019 |
| | Irbesartan 150mg Tablets, 90 count bottle | 60429-641-90 | B161003 | 09/2019 |
| | | | B161004 | 09/2019 |
| | | | B161006 | 09/2019 |
| | | | B161007 | 09/2019 |
| | | | B161008 | 11/2019 |
| | | | B161009 | 11/2019 |
| | | | B161010 | 11/2019 |
| | | | C161001 | 02/2020 |
| | | | C161003 | 05/2020 |
| | Irbesartan 300mg Tablets, 30 count bottle | 60429-642-30 | GS019036 | 09/2019 |
| | | | GS019073 | 09/2019 |
| | | | GS021472 | 11/2019 |
| | | | GS021530 | 11/2019 |
| | | | GS022234 | 02/2020 |
| | Irbesartan 300mg Tablets, 90 count bottle | 60429-642-90 | B162009 | 09/2019 |
| | | | B162010 | 09/2019 |
| | | | B162011 | 09/2019 |

| Company | Product | NDC | Lot | Expiration |
|---|---|---|---|---|
| | | | B162012 | 11/2019 |
| | | | B162013 | 11/2019 |
| | | | B162014 | 11/2019 |
| | | | B162015 | 11/2019 |
| | | | C162001 | 02/2020 |
| Prinston Pharmaceutical Inc., dba Solco Healthcare LLC | Irbesartan 300mg Tablets, 90 count bottle | 43547-376-09 | 331B18009 | 02/2021 |
| | Irbesartan and Hydrochlorothiazide (HCTZ) 300mg/12.5mg Tablets, 30 count bottle | 43547-331-03 | 327A18001 | 03/2021 |
| | | | 327A18002 | 03/2021 |
| | Irbesartan and Hydrochlorothiazide (HCTZ) 300mg/12.5mg Tablets, 90 count bottle | 43547-331-09 | 327B18008 | 03/2021 |
| | | | 327B18009 | 03/2021 |
| | Irbesartan and Hydrochlorothiazide (HCTZ) 150mg/12.5mg Tablets, 30 count bottle | 43547-330-03 | 325D18004 | 03/2021 |
| | | | 325D18005 | 03/2021 |
| | Irbesartan and Hydrochlorothiazide (HCTZ) 150mg/12.5mg Tablets, 90 count bottle | 43547-330-09 | 325B18004 | 03/2021 |

JS 44 (Rev. 06/17)

# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

**I. (a) PLAINTIFFS** MAINE AUTOMOBILE DEALERS ASSOCIATION, INC. INSURANCE TRUST, on behalf of Itself and all others similarly situated

**(b)** County of Residence of First Listed Plaintiff Kennebec County, Maine
*(EXCEPT IN U.S. PLAINTIFF CASES)*

**(c)** Attorneys *(Firm Name, Address, and Telephone Number)*
LOWEY DANNENBERG, P.C.
44 S. Broadway, Suite 1100, White Plains, NY 10601
(914) 997-0500

**DEFENDANTS** A-S MEDICATION SOLUTIONS LLC, et al.,

County of Residence of First Listed Defendant Dodge County, Nebraska
*(IN U.S. PLAINTIFF CASES ONLY)*

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

## II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

## III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
*(For Diversity Cases Only)*

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated *or* Principal Place of Business In This State | ☐ 4 | ☒ 4 |
| Citizen of Another State | ☒ 2 | ☐ 2 | Incorporated *and* Principal Place of Business In Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

## IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**TORTS**

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

**CIVIL RIGHTS**
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

**PRISONER PETITIONS**

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

**FORFEITURE/PENALTY**
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

**LABOR**
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

**IMMIGRATION**
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

**SOCIAL SECURITY**
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

**FEDERAL TAX SUITS**
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

**OTHER STATUTES**
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

## V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d)

Brief description of cause:
Cost recovery action by third party payors in connection with [redacted]-contaminated drugs

## VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

**DEMAND $**

CHECK YES only if demanded in complaint:
**JURY DEMAND:** ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE _____ DOCKET NUMBER _____

DATE
1/30/2019

SIGNATURE OF ATTORNEY OF RECORD
/s Peter D. St. Phllip, Jr.

**FOR OFFICE USE ONLY**

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

# INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

**I.(a)** **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

**(b)** **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

**(c)** **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

**II.** **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

**III.** **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

**IV.** **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

**V.** **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
**PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

**VI.** **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

**VII.** **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

**VIII.** **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.